

Art Unit: 1629

### EXAMINER'S AMENDMENT

An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this Examiner's amendment was given in a telephone interview with Sean M. Coughlin (Reg. No. 48,593) on Thursday, March 31, 2011.

The following amendments have been authorized:

#### **IN THE CLAIMS:**

##### **Please amend Claim 40 in the following manner:**

---Claim 40 (Currently Amended): A method of treating a hyperproliferative disease of the skin consisting of administering to a patient in need of treatment for a hyperproliferative disease of the skin a pharmaceutical composition consisting of carbenoxolone and one or more pharmaceutically acceptable excipients, wherein the hyperproliferative disease of the skin is selected from the group consisting of psoriasis, acne vulgaris, actinic keratosis, solar keratosis, squamous carcinoma in situ, ~~skin cancers and pre-malignant conditions of the skin,~~ ichthyoses, hyperkeratosis and Darier's disease ~~disorders of keratinization.~~---

##### **Please amend Claim 43 in the following manner:**

---Claim 43 (Currently Amended): The method of claim 40, wherein the hyperproliferative disease of the skin ~~disorder of keratinization~~ is Darier's disease.---

##### **Please amend Claim 47 in the following manner:**

---Claim 47 (Currently Amended): The method of claim 44, wherein the hyperproliferative disease of the skin ~~disorder of keratinization~~ is Darier's disease.---

### REASONS FOR ALLOWANCE

The following is an Examiner's statement of reasons for allowance: Applicant has established on the record that the term "pharmaceutically acceptable excipient" is an auxiliary compound or chemical employed to assist in the delivery and/or formulation of an active pharmaceutical ingredient and, therefore, excludes other compounds that would be considered a drug or medicine or active pharmaceutical ingredient of a formulation. Accordingly, the prior art to Burchardt et al., which describes the administration of a topical therapy of carbenoxolone with an active LTD<sub>4</sub> receptor antagonist used to potentiate the anti-inflammatory activity of the carbenoxolone agent for the treatment of psoriasis, does not render the instant claims obvious. For these reasons, the instant claims distinguish over the reference to Burchardt et al. as applied in the previous Office Action dated July 20, 2010.

Any comments considered necessary by Applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

#### **Claims 40-47 are allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds Draper whose telephone number is (571)272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey S. Lundgren can be reached on (571)-272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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/Leslie A. Royds Draper/  
Primary Examiner, Art Unit 1629

March 31, 2011